BALLOON STENT ASSEMBLY SYSTEM AND METHOD

TECHNICAL FIELD OF THE INVENTION

The present invention relates to medical implant devices. Specifically, the invention relates to a balloon encapsulated by an expandable stent for intravascular deployment.

BACKGROUND OF THE INVENTION

[0001] Balloon catheters are used in a variety of medical therapeutic applications including intravascular angioplasty. For example, a balloon catheter device is inflated during PTCA (percutaneous transluminal coronary angioplasty) to dilate a stenotic blood vessel. The stenosis may be the result of a lesion such as a plaque or thrombus. After inflation, the pressurized balloon exerts a compressive force on the lesion thereby increasing the inner diameter of the affected vessel. The increased interior vessel diameter facilitates improved blood flow. Soon after the procedure, however, a significant proportion of treated vessels re-narrow.

[0002] To prevent restenosis, short flexible cylinders, or stents, constructed of metal or various polymers are implanted within the vessel to maintain lumen size. The stent acts as a scaffold to support the lumen in an open position. Various configurations of stents include a cylindrical tube defined by a mesh, interconnected stents or like segments. Some exemplary stents are disclosed in U.S. Patent No. 5,292,331 to Boneau, U.S. Patent No. 6,090,127 to Globerman, U.S. Patent No. 5,133,732 to Wiktor, U.S. Patent No. 4,739,762 to Palmaz and U.S. Patent No. 5,421,955 to Lau. Balloon-expandable stents are mounted on a collapsed balloon at a diameter smaller than when deployed. During the procedure, the balloon stent catheter is advanced through a network of tortuous blood vessels. Furthermore, the balloon stent catheter also may encounter narrowed lumens or

lumens that are obstructed. Once at the desired site, the balloon is inflated and expands the stent to a final diameter. After deployment, the stent remains in the vessel and the balloon catheter is removed.

[0003] While the balloon stent catheter is moved longitudinally through the network of vessels, position of the stent should be maintained. The stent may become dislodged off the balloon or if it is shifted on the balloon, it may not expand fully along its length. Current strategies for retaining the stent on the balloon include: plastically deforming the stent so that it is crimped onto the balloon; increasing the friction forces between the stent and balloon by modifying the balloon through heat, pressure, or chemical or adhesive means; adding retainers that physically prevent the stent movement; or combinations thereof.

[0004] U.S. Patent No. 4,950,227 to Savin discloses a strategy for stent retention that utilizes end caps mounted on the catheter. The end caps are adapted to temporarily engage the ends of the stent while permitting the stent ends to release when the stent is expanded.

[0005] U.S. Patent Nos. 5,836,965 and 6,159,229 issued Dec. 12, 2000 to Jendersee *et al.* discloses a strategy for stent retention utilizing a heating process to deform the balloon about the stent while the balloon is heated and preferably pressurized. The balloon expands around and within gaps of the stent causing it to adhere. The balloon continues to adhere as it is cooled and its shape is set. Furthermore, retainers may be placed at the distal and/or proximal ends of the stent.

[0006] The U.S. Patent No. 5,976,181 issued Nov. 2, 1999 to Whelan *et al.* discloses a strategy for stent retention utilizing a chemical process to deform the balloon. The balloon is sheathed and pressurized followed by the addition of solvent. The process produces radial projections in the balloon surface that are forced around the ends and within the gaps of the stent. The balloon is depressurized and maintains a permanent shape that interlocks with the stent.

[0007] The U.S. Patent No. 6,066,156 issued May 23, 2000 to Yan discloses a strategy for stent retention utilizing a temperature activated releasable adhesive. The tacky adhesive coated balloon increases stent retention. The adhesive becomes non-tacky at a transformation temperature just above that of human blood. After positioning the stent at the desired site, a warming solution is introduced to transform the adhesive. The adhesive becomes non-tacky and releases the stent.

[0008] The U.S. Patent No. 6,110,180 issued Aug. 29, 2000 to Foreman *et al.* discloses a strategy for stent retention utilizing an expandable member having outwardly extending protrusions. The protrusions are formed by applying dots of an adhesive material on the outer surface of the expandable member. Alternatively, the protrusions may be integrally formed with the balloon. The stent is crimped onto the expandable member such that the protrusions extend into the gaps of the stent. After deployment, the protrusions are retracted from the gaps thereby releasing the stent.

[0009] The disclosed and other strategies may provide adequate stent retention for a number of older stent designs. A current trend for stent design, however, calls for an increasing density of mesh struts or segments forming the scaffolding to enhance mechanical strength, reduce failure and increase the stent to artery ratio. The newer stents have smaller interstices, or gaps, between the mesh struts or segments. As a result, many of the existing strategies cannot provide sufficient stent retention required during intravascular maneuvers. For example, balloons deformed by a heat/pressure process may not extend sufficiently into the smaller gaps to adequately secure the stent on the balloon.

[0010] When looking at ways to improve stent retention, one must not compromise the design considerations of longitudinal flexibility and low profile of the stent for deliverability. Other limitations of current stent retention strategies include: mechanical retainers and permanent sheaths that may increase unit profile and cost; crimping which may permanently deform the stent and hinder deployment; tacky adhesives that may complicate catheter advancement through a vessel; and multiple layers that may increase

balloon rigidity and cost. Therefore, it would be desirable to achieve a balloon-stent assembly that is compatible with newer stent designs and to overcome the aforementioned and other disadvantages.

SUMMARY OF THE INVENTION

[0011] One aspect of the invention provides stent delivery system comprising a balloon, including an outer layer portion, and a stent. The stent covers at least 55 percent of the outer layer portion. The outer layer portion flows into gaps formed in the stent when the balloon delivery system is heated to a predetermined temperature securing the stent on the balloon. The predetermined temperature may range from about 50 to 70 degrees Celsius. The balloon comprises at least one outer layer and at least one inner layer, the outer layer portion comprising the outer layer. The outer and inner layers may comprise a co-extruded laminate. Furthermore, the outer layer may comprise a tie layer and/or a functionalized material. The functionalized material is not tacky at temperatures below the predetermined temperature and may consist of polyethylene.

[0012] Another aspect of the invention provides a balloon stent delivery system comprising a balloon including at least one non-tacky outer layer and at least one inner layer, and a stent disposed on the outer layer. When the balloon is heated at a predetermined temperature an outer layer portion flows into gaps formed in the stent while the inner layer does not flow. The outer layer comprises a first material and the inner layer comprises a second material different from the first material. The stent may cover at least 55 percent of the outer layer and the balloon may provide at least 200 gf (gram force) of a stent retention force. The stent may cover at least 70 percent of the outer layer and the balloon may provide at least 300 gf of a stent retention force. The stent may cover at least 90 percent of the outer layer and the balloon may provide at least 90 gf of a stent retention force.

[0013] Yet another aspect of the invention provides for a method of retaining a stent on a balloon comprising: mounting the stent onto the balloon, the stent including gaps formed

therein, sheathing the mounted stent and balloon, heating the balloon, and flowing an outer layer of the balloon into the gaps formed in the stent while an inner layer of the balloon does not flow. The balloon may be pressurized. The outer layer may flow into a predetermined or a random arrangement of gaps.

[0014] The foregoing and other features and advantages of the invention will become further apparent from the following detailed description of the presently preferred embodiments, read in conjunction with the accompanying drawings. The detailed description and drawings are merely illustrative of the invention rather than limiting, the scope of the invention being defined by the appended claims and equivalents thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] Figure 1 is a sectional view of one embodiment of a balloon stent assembly system disposed on a catheter according to the present invention;

[0016] Figure 2 is a sectional view of the balloon stent assembly system of Figure 1 after an outer layer portion has flowed into stent gaps;

[0017] Figure 3 is a cross-sectional view of the balloon stent assembly system of Figure 2; and

[0018] Figure 4 is a sectional view of a sheathed balloon stent assembly of the present invention.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENT

[0019] Referring to the drawings, illustrated in Figures 1 and 2 is one embodiment of a balloon stent assembly **10** disposed on a catheter **40** in accordance with the present

invention. The balloon stent assembly **10** comprises a balloon **20**, including an outer layer portion **22**, and a stent **30**, disposed on the balloon **20**. The stent **30** covers at least 55 percent of the outer layer portion **22**. The outer layer portion **22** is defined as the part of the balloon **20** or its components that are in operable contact with the stent **30**, and the members **32**, and gaps **33** that comprise the stent **30**.

[0020] The balloon **20** is shown in a collapsed position and may be inflated during stent **30** deployment. The stent **30** comprises a lattice configuration of members **32**, fabricated from metal or other structural material, and gaps **33** formed between the members **32**. The stent **30** may additionally be crimped onto the balloon to enhance retention. The balloon stent assembly **10** is typically delivered to a desired site utilizing a standard guidewire for negotiation of vessel pathways.

[0021] The balloon **20** comprises at least one non-tacky outer layer **22** and at least one inner layer **21**. The outer **22** and inner layers **21** may comprise a co-extruded laminate. Furthermore, the outer layer may comprise a tie layer and/or a functionalized material. An example of a co-extruded trilayer laminate including a tie layer is disclosed in U.S. Pat. No. 6,165,166 issued to Samuelson *et* al. and is incorporated herein in its entirety by reference thereto. As shown in Figures 1 and 2, the outer layer **22** is disposed on a limited area of the inner layer **21**. It can be appreciated that the outer layer **22** may cover varying proportions and configurations of the inner layer **21** to achieve desirable stent retention.

[0022] The inner layer **21** may be fabricated from a variety of biocompatible compliant or non-compliant materials or blends including nylon-12 and Selar®. The functionalized material and potentially the tie layer are not tacky at temperatures below the predetermined temperature and may comprise a polyethylene such as Bynel® or Plexar®. Alternatively, the inner **21** and outer layers **22** may be comprised of a number of material(s) or layer(s) that adequately provides both support and stent retention.

[0023] When the balloon stent assembly is heated to a predetermined temperature, the outer layer portion **22** flows into gaps **33** formed in the stent **30**. The predetermined temperature may range from about 50 to 70 degrees Celsius. The predetermined temperature will vary based on characteristics of the functionalized material. For example, a temperature of 100 degrees Celsius may be required to flow a functionalized material adequately into the gaps **33**.

[0024] Figures 2 and 3 are representations of one embodiment after the outer layer portion **22** has flowed into the gaps **33**. The flowed outer layer portion **22** retains the stent **30** on the balloon **20** during intravascular movement. The relatively low viscosity of the outer layer portion **22** allows for flow into smaller gaps **33** and, thus, enhances stent **30** retention. In addition, the outer layer portion **22** is adaptably capable of flowing into a range of gap **33** sizes present within the stent **30**.

[0025] In another embodiment, an outer layer portion **22** flows into gaps **33** while an inner layer **21** does not flow when heated to the predetermined temperature. Furthermore, the outer layer **22** comprises a first material and the inner layer **21** comprises a second material different from the first material.

[0026] Yet another embodiment includes a method of retaining a stent **30** on a balloon **20** comprising: mounting the stent **30** onto the balloon **20**, the stent **30** including gaps **33** formed among members **32** that covers at least 55 percent of the balloon, sheathing the mounted stent **30** and balloon **20**, heating the balloon **20**, and flowing an outer layer **22** of the balloon **20** into the gaps **33** formed in the stent **30** while an inner layer **21** of the balloon **20** does not flow. The balloon **20** may be pressurized to facilitate the flow of the outer layer **22** into the gaps **33**. This heat set procedure may be similar to the processes disclosed by U.S. Pat. No. 6,032,092 issued to Shin and U.S. Pat. No. 6,159,229 issued to Jendersee *at al.* and are incorporated herein in their entirety by reference thereto.

[0027] In such a procedure, a tube made of a sufficiently rigid material such as metal, plastic, or the like is placed around the balloon stent assembly **10** to maintain a limited

inflation size. The sheathed balloon stent assembly (shown in Figure 4) may then be pressurized with an inflation pressure, for example, in the range of approximately ten to twenty pounds per square inch. The sheathed assembly is then heated to the predetermined temperature for a time sufficient to allow adequate flow of the outer layer portion **22** into the gaps **33**. The balloon **20** portion or outer layer portion **22** may flow into a predetermined or a random arrangement of gaps **33** depending on the stent **30** design and outer layer **22** composition. Furthermore, the stent assembly may include a distal retainer 36 and/or a proximal retainer 38 to further secure the stent to the balloon. The retainers also create a transition between the balloon and stent area of delivery device and the distal and proximal surfaces of the delivery device of the encapsulated stent assembly. The retainers may be formed by the balloon itself during the encapsulation process, with the configuration of the formed retainers determined by the dimensions of the spaces between the sheath 34 and the stent members 32. Upon completing the flowing step, the sheathed balloon stent assembly is allowed to cool to room temperature and the tube sheath is removed. The functionalized material is not tacky at this point thereby preventing any exposed portion from adhering to vessel surfaces during medical procedures.

[0028] The stent **30** can be of a typical stent design, including wire and tube designs, and may expand during deployment. The present invention is compatible with older stent designs such as those disclosed in, for example, U.S. Pat. No. 5,649,952 issued to Lam and U.S. Pat. No. 5,514,154 issued to Lau *et al.* In addition, improved stent retention is demonstrated for newer stent designs covering in excess of 55 percent of the outer layer portion **22**.

[0029] The current trend for stent design calls for an increasing density of members **32** to enhance mechanical strength and reduce failure. The novel stents have smaller interstices, or gaps **33**, between the members **32**. The balloon **20** area covered by the stent **30** generally influences stent retention force. The retention force typically diminishes, particularly with current retention technology, as the gaps **33** decrease in size.

Balloon stent assemblies **10** made in accordance with the present invention, however, provides a greater retention force when compared to the existing designs.

[0030] Experiments using balloon stent assemblies **10** made in accordance with the present invention reveal a stent retention force of 200 gf (gram force) or greater when the stent **30** covers about 55 to 70 percent of the outer layer portion **22**. Stents covering about 70 to 90 percent provide at least 300 gf, and stents covering about 90 percent and greater provide at least 90 gf of retention force. Therefore, the present invention provides a superior stent retention force and may reduce the chance of stent slippage or loss during intravascular movement.

[0031] For illustrative purposes, the following table gives approximate stent retention force for several newer stent designs. The table outlines: the outer portion coverage percentage, retention force using existing balloon stent retention technology (retention A), retention force using a balloon stent assembly made in accordance with the present invention (retention B), and percent difference of retention A to B (% Δ).

TABLE I

Stent	Covered Area (%)	Retention A (gf)	Retention B (gf)	% Δ
1	58	200	220	+ 10
2	65	72	204	+ 183
3	72	159	399	+ 151
4	72	136	318	+ 134
5	91	40	94	+ 135

[0032] The invention and its detailed embodiments are described as applied for use in coronary arteries, i.e. during PTCA. Those skilled in the art will appreciate that the invention may be applied to devices for use in other body lumens as well, such as peripheral arteries and veins. Also, the invention is described with respect to the balloon

stent assembly **10** disposed on a portion of a catheter **40**. The invention may be mounted on any device capable of delivering the assembly to a required site.

[0033] While the embodiments of the invention disclosed herein are presently considered to be preferred, various changes and modifications can be made without departing from the spirit and scope of the invention. The scope of the invention is indicated in the appended claims, and all changes that come within the meaning and range of equivalents are intended to be embraced therein.